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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,339	09/10/2002	Paul Sherwood	13596-003US1	2886

7590 01/26/2005

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,339	SHERWOOD ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-20-04 (RCE Request)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-27* is/are rejected.

7)☒ Claim(s) *28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Priority

Applicant is requested to amend the first line of the specification to indicate that this application is a 371 of PCT/GB00/03490, filed 09/12/2000.

Duplicate Claim Warning

Applicant is advised that should claim 15 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Furthermore, the following sets of claims also appear to be duplicates:

i) 17 and 22;

ii) 18 and 23;

iii) 19 and 24; and

iv) 25 and 26.

Previous Rejections

Unless explicitly maintained hereinunder, all prior rejections are withdrawn.

Indefiniteness Rejection (New)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite insofar as it recites an improper Markush group. The Markush group is improper because it fails to use the required "selected from" language. Accordingly, in order to overcome this rejection, the claimed phrase "disorder from" should be changed to read --- disorder selected from the group consisting of ---

Anticipation Rejection (Previous)

Claims 10-15 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Hyodo et al (USP 5,260,289). See Paper No. 8.

This rejection is maintained.

Applicant argues that since calcium pantothenate is not listed among the "active ingredients" in Neo Vitacain, the prior art provides no basis to conclude that calcium panthothenate possesses analgesic properties or would be an active agent for the treatment of pain. Moreover, Applicant argues, there is no indication in the prior art that calcium pantothenate is useful for treating inflammation. Stated alternatively, the prior art does not disclose administration of calcium panthothenate "as the single and exclusive active ingredient for treating pain and inflammation as is required by claim 10 as amended." (Remarks, p. 7, second full ¶). Furthermore, Applicant argues that the term "consisting essentially of" limits the claims to pantothenic acid or its derivatives, because other materials which materially affect the basic and novel characteristics of the claimed invention are excluded thereby.

These arguments have been carefully considered but are not persuasive. The instant claims, as currently constructed, do not specifically recite that pantothenic acid or its derivatives function in any particular capacity, be it as an anti-inflammatory, an analgesic, or a combination thereof. All that is required is that pain and inflammation be treated by administering a composition "consisting essentially

of" an "effective amount" of a pantothenic acid. The calcium pantothenate of the prior art is present, as part of a composition, in an amount "effective" for carrying out the prior art therapies. And contrary to Applicant's position, the additional ingredients in the prior art compositions do not appear to "affect the basic and novel characteristics" of the claimed invention. The additional ingredients of the prior art would not affect the basic pain and inflammation relieving characteristics of the instant compositions; sodium salicylate (see the prior art at col. 1, line 45) for example, is a known anti-inflammatory, analgesic and pain reliever.

Applicant also contends that the prior art does not suggest, teach or disclose administering a local anesthetic as a separate injection as required by instant claims 15 and 20. The examiner believes this assertion to be unfounded, given the disclosure provided at col. 4, lines 60-62 of the prior art to administer the local anesthetic dibucaine as a separate composition.

Obviousness Rejection (New)

1) Claims 16, 21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al (USP 5,260,289) in view of Speck (USP 4,870,061).

The primary reference has been discussed previously and in detail throughout prosecution of this application, and differs from the instant claims insofar as it is silent regarding the co-administration of glucosamine.

It is well-known to administer glucosamine by direct injection to affected joints in order to reduce pain and wear associated with arthritis and other inflammatory joint disorders. See the background discussion of col. 1, lines 46-48 and 60-66 of the secondary reference. (Direct injection to the affected joint is reasonably implied by the prior art's direction to use parenteral injection in a manner which maximizes bioavailability.) That reference differs from the instant claims because it is silent regarding pantothenic acid.

It would have been obvious to have provided such injections to the patients of the primary reference, motivated by the desire to reduce wear and further reduce pain, as taught by the secondary

reference. Regarding instant claim 27, while the primary and secondary references disclose separate injections of each, it would have been obvious to have combined the pantothenic acid compound and glucosamine into a single injectable composition for administration to those patients particularly uncomfortable with injections, motivated by the desire to minimize the number of injections required. This position is fully consistent with established precedent. See for example In re Kerkhoven, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). (Holding that it is generally obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.)

2) Claims 17-19 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al (USP 5,260,289) in view of Hills (USP 6,133,249).

The primary reference has been discussed previously and in detail throughout prosecution of this application, and differs from the instant claims insofar as it silent regarding separate injections of a joint lubricant comprising phosphatidyl glycerol, dipalmitoyl-phosphatidyl choline, or mixtures thereof.

It is well-known in the art to administer joint lubricants comprising phosphatidyl glycerol or dipalmitoyl-phosphatidyl choline by direct injection to affected joints in order to reduce pain and wear associated with arthritis and other inflammatory joint disorders. See the secondary reference, especially at col. 5, lines 32-43 and 62-65. That reference differs from the instant claims because it is silent regarding pantothenic acid.

It would have been obvious to have provided such injections to the patients of the primary reference, motivated by the desire to reduce wear and further reduce pain, as taught by the secondary reference. Insofar as the secondary reference does not specifically disclose mixtures of phosphatidyl glycerol and dipalmitoyl-phosphatidyl choline, it would have been self-evident to have combined the two, the idea for combining them flowing logically from their having been individually taught in the prior art. See In re Crockett, 126 USPQ 186, 188 (C.C.P.A. 1960).

3) Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al (USP 5,260,289).

This rejection presumes, purely *arguendo* and for the sake of completeness of prosecution only, that the teaching provided at col. 4, lines 60-62 of the prior art (see the last paragraph of the "Anticipation" rejection above) is too non-specific and general in nature to specifically disclose separate injection of the local anesthetic dibucaine in an anticipatory fashion. In that case, it would still have been obvious in a self-evident manner to have separately administered additional anesthetic to those patients uncomfortable with injections, numbing the affected area with a smaller dosage of anesthetic prior to subsequent administration of the larger therapeutic dosage, motivated by the desire to increase patient comfort.

Allowable Subject Matter

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not fairly suggest, teach or disclose using an effective dosage of 500mg pantothenic acid. (This dosage is orders of magnitude higher than the amounts used by Hyodo et al.)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614